

REMARKS

In the Office Action, Claims 6-14, 16-18 and 22 have been rejected under 35 U.S.C. § 112, second paragraph; and Claims 1-24 have been rejected under 35 U.S.C. § 102 and/or § 103. Claims 17, 18 and 22 have been amended. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

At the outset, the Patent Office has withdrawn the finality of the previous Office Action dated January 10, 2003 and thus, has reopened prosecution on the merits regarding the above-referenced patent application. In this regard, the Examiner has indicated that the finality of the Office Action has been withdrawn in view of the rejection of Claims 6-14, 16-18 and 22 under 35 U.S.C. § 112, second paragraph.

More specifically, the Patent Office questions the dependency of Claim 22; and further alleges that the subject matter as defined in Claims 6-14, 16-18 and 22 is vague and indefinite. With respect to the dependency issue regarding Claim 22, this claim has been amended as previously discussed. Claims 17 and 18 have also been amended to address dependency. Applicants note for the record that these changes to the claims were made for clarification purposes and further not intended to narrow and/or cancel any claimed subject matter in view of same. In view of same, Applicants believe that this issue has been addressed.

With respect to the alleged clarity issue regarding Claims 6-14, 16-18 and 22, Applicants believe that the Patent Office's position is improper. Of these claims, Claim 6 is an independent claim that recites an anti-plaque chewing gum that includes a water insoluble portion; and a water soluble portion including an emulsifier triclosan and a surfactant. Claims 7-14 each depend from Claim 6, either directly or indirectly. Claims 16-18 and 22 depend from Claim 15 that recites a method for reducing plaque, including the step of orally applying to the mouth an emulsion that includes an emulsifier, triclosan and a surfactant. Claim 16 further recites that the emulsion is in the form of a chewing gum; Claim 17 further recites that the chewing gum is chewed for at least five minutes; and Claim 18 further recites that the chewing gum is chewed at least three times per day. As previously discussed, Claim 22 was amended to further recite that the emulsion of Claim 15 is in the form of one or more pieces of gum and wherein each piece of gum includes approximately 1mg to about 6mg of triclosan.

Applicants believe that each of the claims at issue are sufficiently supported in the specification such that one skilled in the art should readily understand the scope and meaning of same. For example, the specification provides that the present invention in an embodiment includes an anti-plaque chewing gum that includes a water insoluble portion and a water soluble portion, including an emulsifier, triclosan and a surfactant. See, specification, page 2, lines 15-17. The specification further provides that the preferred embodiment of the present invention is the use of the emulsion in a chewing gum and most preferably the emulsion would be included in the pellet coating of a sugarless chewing gum. See, specification, page 5, lines 1-5. This would clearly suggest to one skilled in the art a coating for a gum that includes the claimed emulsion is one example that is illustrative of the claimed invention. Indeed, the specification also details numerous examples of chewing gum representative of the claimed invention beginning on page 5 and further including specific examples beginning on page 9 of the specification. Contrary to the Patent Office's position, Applicants respectfully submit that the scope and content of the claims at issue are clearly defined as presently pending.

Based on at least these reasons, Applicants believe that Claims 6-14, 16-18 and 22 satisfy the requirements of 35 U.S.C. § 112, second paragraph. Therefore, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 1-24 have been rejected under 35 U.S.C. § 102 and/or § 103. More specifically, the Patent Office has relied on *Libin I*, *Andersen* and/or *Hill* in support of the anticipation and/or obviousness rejections. Applicants believe that the prior art rejections are improper.

Even if combinable, Applicants believe that the cited art fails to disclose or suggest a number of features of the claimed invention. For example, nowhere does the cited art disclose or suggest an anti-plaque emulsion that includes an emulsifier, triclosan and a surfactant, products thereof (e.g., chewing gum) and methods of employing same as required by the claimed invention. Of the pending Claims 1-24, Claims 1, 6 and 15 are the sole independent claims. Independent Claim 1 recites an anti-plaque emulsion that includes an emulsifier, triclosan and a surfactant; independent Claim 6 recites an anti-plaque chewing gum that includes, in part, a water soluble portion, including an emulsifier, triclosan and a surfactant; and Claim 15 recites a

method for reducing plaque that includes orally applying to the mouth an emulsion that includes an emulsifier, triclosan and a surfactant.

The present invention provides an improved anti-plaque emulsion that contains actives, such as antimicrobial agents, that can be employed to reduce plaque build-up on dental surfaces. In this regard, saliva can disperse the emulsion across the dental surfaces, thus providing the actives with a more complete oral contact of the plaque-covered surfaces. Further, the actives within the emulsion can be effective against plaque at reduced levels, thus also minimizing negative sensory effects due to the active. For example, an emulsion that includes reduced levels of triclosan has been demonstrated to be an effective anti-plaque emulsion, such as incorporated in a chewing gum product. Moreover, negative sensory effects associated with the use of triclosan, such as bad taste and staining, can be minimized. This can increase the likelihood of regular use, thus promoting the reduction of plaque build-up.

With respect to *Libin I*, the Patent Office relies on this reference, on its own, in support of an alleged anticipation rejection of Claims 1, 2, 4, 5, 15, 19 and 23 and an obviousness rejection of Claims 3, 4, 20, 21 and 24. Of these claims, Claims 1 and 15 are the sole independent claims. Clearly, *Libin I* fails to disclose the emulsion features as claimed.

For example, nowhere does *Libin I* disclose an emulsion or its use in relation to its anti-plaque mouth rinse. Indeed, Applicants question how the Patent Office can rely on *Libin I* where *Libin I* discloses a solubilizer that is utilized in a sufficient amount to solubilize triclosan. See, *Libin I*, Claim 1, col. 1 at lines 53-60. In this regard, *Libin I* emphasizes solubilizing, not emulsifying triclosan. This clearly contrasts the claimed invention that includes, in part, an emulsion with an emulsifier, triclosan and a surfactant. Applicants have demonstrated that the emulsion with triclosan at reduced levels can effectively reduce plaque while minimizing negative sensory effects typically associated with use of same.

Further, the Patent Office cannot be permitted to expand the meaning of the solubilizer disclosed in *Libin* to also mean an emulsifier. It is clear that *Libin I* is using Tween 20 only as a solubilizer not as an emulsifier. Moreover, the Examiner is not permitted to use extrinsic evidence to characterize Tween 20 as an emulsifier when the reference is only describing it as a solubilizer. Of course, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1981) (emphasis added). Moreover, “The identical invention must be shown in complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989) (emphasis added).

Yet in spite of the above, the Patent Office continues to rely on the Merck Index to support this anticipation rejection. Indeed, Applicants submit that the Patent Office’s reliance on extrinsic evidence in this case is clearly improper. It is established case law that extrinsic evidence may not be used to “expand the meaning of terms and phrases used in the reference relied upon as anticipatory of the claimed subject matter.” *In re Baxter Travenol Labs.*, 952 F.2d 388 (Fed. Cir. 1991)(emphasis added). Here, it is clear that the Patent Office is attempting to expand the meaning of Tween 20, which is described only as a solubilizer in *Libin I*, to also include an emulsifier based on extrinsic evidence, namely, the Merck Index.

Further, *Libin I* cannot be relied on solely in support of the obviousness rejection of Claims 3, 4, 20, 21 and 24. As previously discussed, each of these claims depends from either of independent Claims 1 and 15 and thus as a matter of law incorporates each of the features of same. Nowhere does *Libin I* disclose, let alone suggest, the emulsion features as claimed.

Again, *Libin I* fails to disclose or suggest the use of an emulsifier to form an anti-plaque emulsion, let alone an anti-plaque emulsion that includes an emulsifier, triclosan, and a surfactant as required by the claimed invention. Indeed, Applicants have found that when in emulsion form, the active ingredients, such as triclosan, are better dispersed across the dental surfaces allowing for complete oral contact with plaque covered surfaces, thus promoting the reduction of plaque on such surfaces. *Libin I* simply describes that water-insoluble triclosan requires the use of a solubilizer to form an aqueous solution. In view of same, one skilled in the art would not be inclined to modify *Libin I* to arrive at the claimed invention. Therefore, Applicants believe that *Libin I* is clearly deficient with respect to the claimed invention.

Moreover, Applicants do not believe that the Patent Office can rely solely on *Libin I* to remedy the deficiencies of *Hill* in support of the rejection of Claims 1, 2, 5-7, 9, 13-16 and 19 under 35 U.S.C. § 103(a). Of these claims at issue, Claims 1, 6 and 15 are the sole independent claims as previously discussed.

At the outset, Applicants question whether *Libin I* and *Hill* should be combined in the first place. Of course, obviousness can only be established by combining or modifying the

teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). The mere fact that the references can normally be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

Clearly, *Hill* provides no such motivation to combine. Indeed, the Patent Office admits that *Hill* fails to disclose the combination of an emulsifier and a surfactant as required by the claimed invention. Further, the Patent Office incorrectly relies on *Libin I* as providing a motivation or suggestion to replace the single surfactant or single emulsifier of *Hill* with the combination thereof. As previously discussed, nowhere does *Libin I* disclose emulsifiers, let alone the combination of emulsifiers and surfactants. The clear emphasis of *Libin I* relates to solubilizing agents, such as triclosan, in order to enhance anti-bacterial activity. *See, Libin I*, col. 3, lines 53-60. Even if combinable, *Hill* and *Libin I* are still deficient with respect to an anti-plaque emulsion that includes an emulsifier, triclosan and a surfactant. Indeed, Applicants have demonstrated that the claimed emulsion can be effectively used to reduce plaque at reduced triclosan levels as previously discussed. Therefore, *Hill* and *Libin I*, alone or even if combinable, are deficient with respect to the claimed invention.

The Patent Office also rejects Claims 1-7, 9-11, 13, 15-17 and 19-21 under 35 U.S.C. § 102(b) as allegedly anticipated by *Andersen*. The Patent Office essentially asserts that *Andersen* discloses each and every feature of the rejected claims.

Applicants respectfully submit that the Patent Office has incorrectly relied on *Andersen* as an anticipatory reference. At the outset, the Patent Office's reliance on Merck Index as extrinsic evidence allegedly demonstrating that nonionic Tween and Pluronic surfactants of *Libin I*, *Hill* and *Andersen* function as emulsifiers is clearly contrary to established law. *See*, Final Office Action, p. 15. As discussed above, the Patent Office is not permitted to expand the meaning of terms within a reference using extrinsic evidence.

Further, the clear emphasis of *Andersen*, like *Libin I*, relates to a solubilizing agent to solubilize the active agent, such as triclosan, in order to control the release of said active agent. *See, Andersen*, Claim 1, col. 10 at line 57-61. Indeed, by simply admixing a solubilizer, an

improved release of active agents without an unacceptable softening of the chewing gum can purportedly be provided as further disclosed in *Andersen* at col. 4, lines 19-24. This clearly contrasts the claimed invention that requires, in part, an emulsion that includes an emulsifier, a surfactant and triclosan, with enhanced anti-plaque properties. Based on at least these reasons, *Andersen* is deficient with respect to the claimed invention.

What the Patent Office has done is to apply hindsight reasoning to modify and/or combine the cited art to arrive at the claimed invention. Of course, this is improper. "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 220 USPQ 303, 312-313 (Fed. Cir. 1983). Again, *Libin I* and *Andersen* primarily relate to solubilizers and purported effects thereof. *Hill* primarily relates to the use of a single emulsifier or single surfactant. This clearly contrasts an anti-plaque emulsion that includes an emulsifier, a surfactant and triclosan, products thereof (e.g., chewing gum) and methods for reducing plaque employing same as required by the claimed invention.

Accordingly, Applicants respectfully request that the rejection of Claims 1-24 under 35 U.S.C. § 102 and/or § 103 should be withdrawn.

Applicants note for the record that the Examiner also appears to reject Claims 6-13, 15-18 and 22 in view of *Hill*. See, Office Action, for example, pages 9 and 10. To the extent that these claims are rejected in view of *Hill*, Applicants respectfully submit that *Hill*, alone or even if combinable with the other cited art, is deficient with respect to the claimed invention. Therefore, Applicants believe that the claimed invention is patentable over *Hill* and thus, anticipation and/or obviousness rejections in view of *Hill* would be improper.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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Dated: December 9, 2003